4-19-06

ITW

APR 17 2006 By

500e	E C					PTO/SB/21 (09-04) oved for use through 07/31/2006. OMB 0651-0031
.9	What the Danenwork	Peduction Act of 1995, no ner	ons are required to res			ark Office; U.S. DEPARTMENT OF COMMERCE ation unless it displays a valid OMB control number
ME	ричестию гарегиотк	Trought Trace Tool, no por	10110 a.o 104a.oa to 100	Application		10/566,056
	T	RANSMITT.	AL	Filing Date		January 25, 2006
		FORM	•	First Named	Inventor	Bruce E. Reidenberg
	(to be use	ed for all correspondence afte	r initial filing)	Art Unit		N/A
	,	,	<b>3</b> ,	Examiner N	ame	Not Yet Assigned
	Total Numbe	r of Pages in This Submiss	sion	Attorney Do	cket Numb	02755/100J553-US1
		EN	ICLOSURES	(Check all	that app	oly)
	Fee Transr	nittal Form	Drawing(s)			After Allowance Communication to TC
	Fee	Attached	Licensing-rel	ated Papers		Appeal Communication to Board of Appeals and Interferences
<b></b> -	Amendmer	nt/Reply	Petition			Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
	After	Final	Petition to Co			Proprietary Information
	Affida	avits/declaration(s)		rney, Revocati orrespondence		Status Letter
	Extension	of Time Request	Terminal Disc	claimer		X Other Enclosure(s) (please Identify below):
	Express Al	bandonment Request	Request for	Refund		PTO SB/08 (3 pages) with 25 references (Tabs 13-37) attached;
	x Information	n Disclosure Statement	CD, Number	of CD(s)	<del></del>	Certificate of Express Mailing; Return Receipt Postcard
وسلمه	Certified C Document	opy of Priority (s)	Landso	cape Table on	CD	
		issing Parts/ Application	Remarks			
		y to Missing Parts under FR 1.52 or 1.53				
						. 11.77.2.19.4.2.2
		SIGNAT	URE OF APPLICA	ANT, ATTOR	RNEY, OR	RAGENT
	Firm Name	DARBY & DARBY F	<sup>2</sup> .C.			
	Signature	Shelly An	·			
	Printed name	Shelly M. Bujikawa			-	
	Date	April 17, 2006			Reg. No.	56,190
,						



Application No. (if known): 10/566,056

Attorney Docket No.: 02755/100J553-US1

## Certificate of Express Mailing Under 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, Airbill No. in an envelope addressed to:

= 778825234 - us

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

on April 17, 2006

B.w.	Lea
Signature	
B.w. Le	E &
Typed or printed name of perso	n signing Certificate
Registration Number, if applicable	Telephone Number

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Transmittal Form (1 page) Information Disclosure Statement (2 pages) PTO SB/08 (3 pages - 37 references) 25 cited References attached (Tabs 13-37) Return Postcard

Docket No.: 02755/100J553-US1

(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application of: Bruce E. Reidenberg et al.

A ....1: -- A: -... NI - . 10/5/// 05/

Application No.: 10/566,056 Confirmation No.: TBA

Filed: January 25, 2006 Art Unit: TBA

For: PREOPERATIVE TREATMENT OF POST

OPERATIVE PAIN

Examiner: Not Yet Assigned

## **INFORMATION DISCLOSURE STATEMENT (IDS)**

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed within three months of the U.S. filing date (37 CFR 1.97(b)(1)).

Applicant has not submitted copies of each cited U.S. patent and U.S. patent application as required by 37 CFR 1.98(a)(2)(i), amended October 2004, as the U.S. Patent and Trademark Office has waived this requirement for all U.S. patent applications. Applicant submits herewith copies of foreign and non-patents in accordance with 37 CFR 1.98(a)(2).

Application No.: 10/566,056 2 Docket No.: 02755/100J553-US1

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Commissioner is authorized to charge any deficiency of up to \$300.00 or credit any excess in this fee to Deposit Account No. 04-0100.

Dated: April 17, 2006

Respectfully submitted,

Shelly M. Fujikawa

Registration No.: 56,190

DARBY & DARBY P.C. P.O. Box 5257

New York, New York 10150-5257

(212) 527-7700

(212) 527-7701 (Fax)

Attorneys/Agents For Applicant

PTO/SB/08a/b (07-05)

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Sub	estitute for form 1449A/B/PT	0	SCLOSURE Filling D PPLICANT First Na Art Unit Examin		Complete if Known
-				Application Number	10/566,056
IN	INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (Use as many sheets as necessary)  heet 1 of 3	SCLOSURE	Filing Date	January 25, 2006	
S		APPLICANT	First Named Inventor	Bruce E. Reidenberg	
_			Art Unit	N/A	
	(Use as many sh	eets as	s necessary)	Examiner Name	Not Yet Assigned
Sheet	1	of	3	Attorney Docket Number	02755/100J553-US1

			U.S. PA	TENT DOCUMENTS		
Examiner	Cite	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where	
Initials*	No.1	Number-Kind Code <sup>2</sup> ( if known)	MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear	
	1.	US-4,806,341	02-21-1989	Chien et al.		
	2.	US-4,119,713	10-10-1978	Carosio		
	3.	US-5,026,556	06-25-1991	Drust et al.		
	4.	US-5,069,909	12-03-1991	Sharma et al.		
	5.	US-5,225,199	07-06-1993	Hidaka et al.	<u> </u>	
	6.	US-5,240,711	08-31-1993	Hille et al.		
	7.	US-5,613,958	03-25-1997	Kochinke et al.		
	8.	US-5,942,530	08-24-1999	Jill Ann Panetta		
	9.	US-20040146547-A1	07-29-2004	Marcenyac et al.		
	10.	US-20040241218-A1	12-02-2004	Lino Tavares		
	11.	US-20040122554-A1	06-24-2004	Howard		
	12.	US-20040126416-A1	07-01-2004	Bruce Reidenberg		

		FOREIC	SN PATENT I	OCUMENTS		
Examiner Initials*	Cite No.¹	Foreign Patent Document  Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Τ <sup>6</sup>
		<del></del> -				

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not \*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \* CITE NO.: Those application(s) which are marked with an single asterisk (\*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. 'Applicant's unique citation designation number (optional). \* See Kinds Codes of USPTO Patent Documents at <a href="www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. \* Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). \* For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. \* Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. \* Applicant is to place a check mark here if English language Translation is attached.

	NON PATENT LITERATURE DOCUMENTS						
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²				
	13.	M.A. NASAR et al., "An Open Study of Sub-lingual Buprenorphine In The Treatment Of Chronic Pain In The Elderly", Curr. Med. Res. Opin. 1986, Vol. 10, No. 4, 1986, pages 251-255					
	14.	G. CAPOGNA et al., "Intrathecal Buprenorphine For Postoperative Analgesia In The Elderly Patient", Anaesthesia, 1988, Vol. 43, pages 128-130					
	15.	K. HANNIBAL, et al., "Preoperative Wound Infiltration With Bupivacaine Reduces Early And Late Opioid Requirement After Hysterectomy", Anesth Analg., 1996, Vol. 83, pages 376-381					
	16.	YOSHIMI INAGAKI et al., "Mode and Site Of Analgesic Action Of Epidural Buprenorphine In Humans", Anesth Analg., 1996, Vol. 83, pages 530-536					

Examiner	Date	
Signature	Considered	

PTO/SB/08a/b (07-05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO  INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (Use as many sheets as necessary)	Complete if Known				
				Application Number	10/566,056
	INFORMATION DISCLOSUR STATEMENT BY APPLICAN	SCLOSURE	Filing Date	January 25, 2006	
S	TATEMENT	BY A	APPLICANT	First Named Inventor	Bruce E. Reidenberg
	STATEMENT BY APPLICA			Art Unit	N/A
	(Use as many sh	eets as	s necessary)	Examiner Name	Not Yet Assigned
Sheet	2	of	3	Attorney Docket Number	02755/100J553-US1

17.	P.TAUZIN-FIN et al., "Effect Of Balanced Analgesia With Buprenorphine On Pain Response And General Anesthesia Requirement During Lithotripsy Procedures", European Journal of anesthesiology, 1998, Vol. 15, pages 147-152	
18.	ERIC C. STRAIN et al., "Acute Effects Of Buprenorphine, Hydromorphone and Naloxone In Methadone-Maintained Volunteers", The Journal Of Pharmacology And Experimental Therapeutics, 1992, Vol. 261, No. 3, pages 985-993	
19.	K. J. SCHUH et al., "Buprenorphine, Morphine and Naloxone Effects During Ascending Morphine Maintenance in Humans", The Journal of Pharmacology And Experimental Therapeutics, 1996, Vol. 278, No. 2, pages 836-845	
20.	H. ADRIAENSEN et al, "A Long-Term Open, Clinical And Pharmacokinetic Assessment Of Sublingual Buprenorphine In Patients Suffering From Chronic Pain", Acta Anaesthesiological Belgica, Vol. 36 March 1985, pages 33-40	
21.	PAUL J. DESJARDINS et al., "The Injectable Cyclooxygenase-2-Specific Inhibitor Parecoxib Sodium Has Analgesic Efficacy When Administered Preoperatively", Anesth Analog, 2001, 93, pages 721-727	
22.	SHARON L. WALSH et al., "Acute Administration of Buprenorphine in Humans: Partial Agonist and Blockade Effects", The Journal Of Pharmacology And Experimental Therapeutics, 1995, Vol. 274, No. 1, pages 361-372	
23.	M. JUHLIN-DANNFELT et al., "Premedication With Sublingual Buprenorphine For Out-Patient Arthroscopy: Reduced Need For Postoperative Pethidine But Higher Incidence Of Nausea", Acta Anaesthesio Scand, 1995, 39, pages 633-636	
24.	RAYMOND A . DIONNE et al., "Suppression Of Postoperative Pain By Preoperative Administration of Ibuprofen In Comparison To Placebo, Acetaminophen, And Acetaminophen, and Acetaminophen Plus Codeine", J. Clin. Pharmacol., 1983, Vol. 23, pages 37-43	
25.	JOHN MENDELSON et al., "Dose Proportionality of 4, 8, 16 And 32 MG Sublingual Buprenorphine Solutions", American Society for Clinical Pharmacology and Therapeutics, 1999, 65, (2), 154, Abstract PII-28	
26.	P. J. FUDALA et al., "A Multi-Site Efficacy Evaluation Of A Buprenorphine/Naloxone Product For Opiate Dependence Treatment", In: Harris, LS (ed). Problems of Drug Dependence, 1998. NIDA Research Monograph #179. Rockville: National Institute On Drug Abuse, 1998a; 105	
27.	ERIC C. STRAIN et al., "Comparison Of Buprenorphine and Methadone In The Treatment Of Opioid Dependence", The American Journal of Psychiatry, July 1994, 151, 7, pages 1025-1030	
28.	HANNU KOKKI et al., "Comparison of Pre- And Postoperative Administration Of Ketoprofen For Analgesia After Tonsillectomy In Children", Pediatric Anesthesia 2002, 12 (2), pages 162-167	
29.	PINTO PEREIRA et al., "Analgesic Effects Of Diclofenac Suppository And Injection After Preoperative Administration", Int. J. Clin. Pharm. Res. 1999, 19(2): pages 47-51	
30.	A.F. FAPONLE, "Management Of Pain After Surgery - A Short Review", Nigerian Journal of Medicine Vol. 10, No. 3, pages 112-115	
31.	Abstract, AKATSUKA et al., "The Relief Of Postoperative Pain By Suppositories Of Buprenorphine or NSAID", Masui, 1996, 45(3):298-303	1

Examiner	Date
Signature	Considered

PTO/SB/08a/b (07-05)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Subs	stitute for form 1449A/B/P1	го		Complete if Known			
_				Application Number	10/566,056		
IN	<b>IFORMATION</b>	N DI	SCLOSURE	Filing Date	January 25, 2006		
S	TATEMENT I	BY A	APPLICANT	First Named Inventor	Bruce E. Reidenberg		
				Art Unit	N/A		
	(Use as many sh	eets as	necessary)	Examiner Name	Not Yet Assigned		
Sheet	3	of	3	Attorney Docket Number	02755/100J553-US1		

3	<ol> <li>Abstract, FLETCHER, "Prevention Of Postoperative Pain", Ann Fr. Anesth Reanim 1998, 17(6), pages 622-632</li> </ol>	<b>₩</b>
3	<ol> <li>Abstract, S. TANAKA et al., "Preoperative Fluribiprofen Provides Pain Relief After Laparoscopic Cholecystectomy", Masui, 1997, 46(5), pages 679-683</li> </ol>	1
3	4. Abstract, A. COLI et al., "Evaluation Of The Effectiveness of NSAIDs In The Prevention Of Postoperative Pain. Comparison Between Pre- And Postoperative Administration Of Sodium Naproxen In Orthopedic Surgery", Minerva Anestesiol 1993, 59(10), pages 531-535	1
3	<ol> <li>Abstract, KAKINOHANA, et al. "Pre-Emptive Analgesia With Intravenous Ketamine Reduces Postoperative Pain In Young patients After Appendectomy: A Randomized Control Study", Masui 2000, 49(10), pages 1092-1096</li> </ol>	1
3	6. F. BREMA et al., "Oral Tramadol And Buprenorphine In Tumor Pain. An Italian Multicentre Trial", Int. J. Clin. Pharm. Res XVI, (4/5), 1996, pages109-116	
3	<ol> <li>A.B. CIRADO, et al., "Reduction of isoflurane MAC with buprenorphine and morphine in rats" Laboratory Animals., 2000, 34 (3):252-9</li> </ol>	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner	Date	
Signature	Considered	 

<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.